K 060464

MAR 2 8 2006

510(k) Summary
Parameter Addition (RDW-SD) to COULTER 5C Cell Control

1. **Submitted By:**

Nancy Nadler
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
11800 SW 147 Avenue, M/C: 31-B06
Miami, Florida 33196-2500
Telephone: (305) 380-4191
FAX: (305) 380-3618

2. **Date Submitted:**

February 21, 2006

3. **Device Name(s):**

3.1 **Proprietary Names**

COULTER® 5C® Cell Control

3.2 **Classification Name**

Hematology quality control mixture
(21 CFR § 864.8625)

4. **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
COULTER® 5C® Cell Control	COULTER® 5C® Cell Control (Cleared as COULTER® PX Cell Control)	Beckman Coulter, Inc.	K912133

5. **Description:**

5C Cell Control is a reference product prepared from treated, stabilized human erythrocytes in an isotonic, bacteriostatic medium. 5C Cell Control also contains a stabilized, platelet-sized component, and fixed erythrocytes to simulate leukocytes. By design, 5C Cell Control confirms and monitors instrument

accuracy and precision performance by providing measurements for counting, sizing, hemoglobin determination and White Blood Cell differentiation using VCS technology.

6. **Intended Use:**

5C Cell Control is a hematology quality control material used to monitor the performance of COULTER hematology analyzers listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents (Refer to your Product Manuals or On-line Help System.)

The assigned values and expected ranges on the TABLE OF EXPECTED RESULTS can be used to monitor instrument performance. This product can also be used to establish your own laboratory mean.

7. **Comparison to Predicate(s):**

COULTER 5C Cell Control with the additional parameter (RDW-SD) is identical to the current COULTER 5C Cell Control. RDW-SD is a derived parameter from the RBC histogram which is obtained on a new COULTER hematology analyzer (510k submission pending). The control product formulation and manufacturing processes were not modified to obtain the additional parameter.

8. **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution. Stability studies of 5C Cell Control with RDW-SD parameter support the Beckman Coulter stability claims of 13 events within 13 days (open vial) and 95 days (closed vial).

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 8 2006

Ms. Nancy Nadler
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
11800 SW 147 Avenue, M/C: 31-B06
Miami, Florida 33196-2500

Re: k060464
Trade/Device Name: COULTER® 5C® Cell Control
Regulation Number: 21 CFR § 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: II
Product Code: JPK
Dated: February 21, 2006
Received: February 22, 2006

Dear Ms. Nadler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: **COULTER® 5C® Cell Control**

Indications for Use:

5C Cell Control is a hematology quality control material used to monitor the performance of COULTER hematology analyzers listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents (Refer to your Product Manuals or On-line Help System.)

The assigned values and expected ranges on the TABLE OF EXPECTED RESULTS can be used to monitor instrument performance. This product can also be used to establish your own laboratory mean.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) OR Over-the-Counter Use _____ Optional Format 1-2-96

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060464